UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS

MARILYN CARLEN,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	**Cause No. 3:19-cv-01304-GCS**
	)	
COLOPLAST CORPORATION,	)	
	)	
Defendant.	)	

MEMORANDUM & ORDER

SISON, Magistrate Judge:

Plaintiff Marilyn Carlen alleges that she was injured by surgical mesh that was developed, designed, manufactured, marketed, distributed, and sold by Defendant Coloplast Corporation. By order dated June 8, 2020, the Court granted in part a motion by Defendant seeking dismissal of Carlen's initial complaint. Carlen was granted leave to file an amended complaint, which she did on July 6, 2020. By motion dated July 20, 2020, Defendant asks the Court to dismiss Counts I, II, and VI of the amended complaint. (Doc. 55). For the reasons delineated below, the Court denies Defendant's motion.

FACTUAL ALLEGATIONS

Plaintiff Marilyn Carlen alleges that Defendant Coloplast Corporation ("Coloplast") develops, designs, manufactures, labels, packages, distributes, markets, supplies, advertises, sells, and otherwise engages in activities related to the sale and distribution of pelvic mesh products. According to Carlen, Coloplast failed to warn her and her healthcare providers adequately regarding attributes of the proper candidates

for their products and about the safest and most effective methods for implantation and use of its pelvic mesh products (Count I). Carlen also alleges that Coloplast failed to exercise reasonable care in the development, design, manufacturing, labeling, packaging, sale, distribution, marketing, advertising, and selling of its products and that the instructions and warnings provided were inadequate (Count II).

Pelvic mesh products, which include Coloplast's mesh, hammock, and sling products and a product called the Aris Transobturator Tape System ("Aris System"), are medical devices used for treating pelvic issues in females, primarily pelvic organ prolapse and stress urinary incontinence. Carlen was implanted with the Aris System on February 2, 2007. Before her surgery, Carlen alleges that both she and her treating physician were exposed to a misleading advertising and marketing campaign that failed to warn or to provide information about what she describes as an unreasonably high rate of complications caused by Coloplast's products. Carlen and her treating physician allegedly were led to believe that Coloplast's products were safe and effective for use in the treatment of pelvic organ prolapse and stress urinary incontinence, but Carlen explains that the products were neither safe nor effective. After her surgery, Carlen began experiencing severe and debilitating pain, and she had to have Coloplast's products surgically removed on November 29, 2017.

As to Count I, Carlen alleges that, at the time the products were marketed and distributed by Coloplast, Defendant knew, and failed to provide warnings, that the products had a high failure rate and that they caused a high rate of infections, abscesses, vaginal erosions and extrusions, and chronic pain. She also claims that Coloplast knew

that it was necessary to remove the mesh products and that there was not a safe, effective procedure for removal of its products. Carlen alleges that, even after receiving notice of bodily injuries caused by the mesh products, Coloplast failed to provide post-marketing or post-sale warnings to physicians or to the women implanted with the products.

In her negligence claim, Carlen alleges that Coloplast neglected its duty to exercise reasonable care in the advertising and sale of its products, including failing to warn and instruct Carlen and other consumers about the dangers associated with its products. Carlen also alleges that Coloplast was derelict in its duty to recruit and train physicians to implant its products. In Count VI, Carlen brings a standalone claim for punitive damages. The parties agree that Carlen's allegations related to punitive damages should not be in a separate, numbered count.

ANALYSIS

To survive a motion to dismiss brought pursuant to Rule 12(b)(6), a complaint must include enough factual content to give the opposing party notice of what the claim is and the grounds upon which it rests. *See Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *Ashcroft v. Iqbal*, 556 U.S. 662, 698 (2009). To satisfy the notice-pleading standard of Rule 8, a complaint must provide a "short and plain statement of the claim showing that the pleader is entitled to relief" in a manner that provides the defendant with "fair notice" of the claim and its basis. *Erickson v. Pardus,* 551 U.S. 89, 93 (2007)(citing *Twombly*, 550 U.S. at 555 and quoting FED. R. CIV. PROC. 8(a)(2)). In ruling on a motion to dismiss for failure to state a claim, a court must "examine whether the allegations in the complaint state a 'plausible' claim for relief." *Arnett v. Webster*, 658 F.3d 742, 751 (7th Cir.

2011)(citing *Iqbal*, 556 U.S. at 677-678). A complaint "must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face," rather than providing allegations that do not rise above the speculative level. *Arnett*, 658 F.3d at 751-752 (internal quotations and citation omitted).

1. Failure to Warn Claim (Count I)

Defendant argues that Plaintiff has failed to state a claim for failure to warn because Defendant did not have a duty to warn Plaintiff of potential dangers with its products and because Plaintiff failed to plead facts demonstrating reliance by her physician on Coloplast's warnings, marketing materials, or other information about the Aris System. Defendant also asks the Court to dismiss Plaintiff's claim to the extent that she alleges there was a post-sale duty to warn, arguing that Illinois does not recognize a post-sale duty to warn.

To prove a claim for failure to warn, a "plaintiff must demonstrate that the manufacturer did not disclose an unreasonably dangerous condition or instruct on the proper use of the product to which the average consumer would not be aware." *Salrerno v. Innovative Surveillance Tech., Inc.*, 932 N.E.2d 101, 109 (Ill. Ct. App. 2010). A duty to warn arises when a "manufacturer has greater knowledge of a product's dangerous propensities than a consumer has." *Hansen v. Baxter Healthcare Corp.*, 723 N.E.2d 302, 311 (Ill. Ct. App. 1999)(citing *Kokoyachuk v. Aeroquip Corp.*, 526 N.E.2d 607 (Ill. Ct. App. 1988)).

The Illinois Supreme Court has explained the duty of a manufacturer of a prescription medical device:

Generally, the manufacturer of a prescription medical device has a duty to

> warn prescribing physicians or other health professionals who may prescribe the device of the product's known dangerous propensities. Likewise, physicians, using their medical judgment, have a duty to convey the warnings to their patients. The duty to warn the healthcare professional, rather than the ultimate consumer or patient, is an expression of the "learned intermediary" doctrine. A corollary of that doctrine is the principle that a prescription medical device manufacturer need not provide a warning of risks already known to the medical community.

Hansen, 764 N.E.2d at 42 (citations omitted). It is true that as the manufacturer of the mesh products, Coloplast's duty to warn lies with warning Carlen's physicians and not Carlen. Carlen, however, alleges that Coloplast failed to warn both her and her treating physician and healthcare providers, and the allegations related to warnings to her healthcare providers are sufficient to plead that a duty existed.

The Court previously ruled that Carlen must plead reliance by her physicians or healthcare providers to state a claim successfully for negligent failure to warn. (*See* Doc. 49, p. 11-12). As the Court explained, in *Norabuena v. Medtronic, Inc.*, an Illinois Appellate Court upheld a trial court order dismissing a failure to warn claim that lacked "specific factual allegations in the complaint asserting that [the plaintiff's] surgeon encountered or relied on any of the asserted promotional marketing." 86 N.E.3d 1198, 1209 (Ill. Ct. App. 2017). At the time, however, Plaintiff did not raise a developed challenge to the application of *Norabuena*, but she now argues that her complaint sufficiently pleads reliance by her physician.

Plaintiff points out that her complaint alleges that her treating physician was exposed to Coloplast's advertising and marketing campaign before her implantation surgery. She also alleges that both she and her physician received the message that

Coloplast intended to send, "to wit: that the Pelvic Mesh Products were safe and effective for use in the treatment of pelvic organ prolapse and stress urinary incontinence." (Doc. 54, ¶ 44, 45). At this stage, Plaintiff is entitled to reasonable inferences. It is reasonable to infer that Carlen's physician relied on marketing attempts that painted Coloplast products as safe and effective and that her physician encountered such marketing information. It is also reasonable to infer that Carlen's physician received the message Coloplast was attempting to send and that as a result, Carlen's physician selected Coloplast products for Carlen's surgery.

As to Carlen's claims about Coloplast's post-sale duty to warn, Illinois generally does not recognize a post-sale duty to warn consumers where defects are discovered after the time of sale. *See Jablonski v. Ford Motor Co.*, 955 N.E.2d 1138, 1160 (Ill. 2011)(stating that "a manufacturer is under no duty to issue postsale warnings or to retrofit its products to remedy defects first discovered after a product has left its control.") (citations omitted). The Illinois Supreme Court acknowledged, however, that a continuing duty to warn may be imposed if, at the time of manufacture of the product, the manufacturer knew or should have known of the danger, but the Court noted that theory was not raised by the plaintiff. *Id*.

Here, Carlen's post-sale allegations address events that occurred after the pelvic mesh products were placed in the stream of commerce:

> Further, *after receiving notice of numerous bodily injuries* resulting from the Pelvic Mesh Products, Coloplast failed to provide such post-marketing or post-sale warnings or instructions that a manufacturer exercising reasonable care should have provided to physicians who implanted the Pelvic Mesh Products or those women who had been implanted with the

> Pelvic Mesh Products that the products were causing an unreasonably high rate of complications . . . .

(Doc. 54, ¶ 64). Carlen, however, also alleges that Coloplast knew, or should have known, of these complications and injuries before its products were sold to and implanted in her. While it presents a close call, the Court will allow Carlen to pursue her post-sale allegations at this time because she sufficiently pleads facts to suggest that there was a continuing duty to warn.

2. Negligence (Count II)

Defendant argues that Count II's negligence claim should be dismissed because it is duplicative of Count I's failure to warn claim. While both claims are predicated on theories of negligence and encompass allegations about deficient warnings, they present alternative theories for recovery. In Count I, Carlen alleges she was harmed by Coloplast's failure to warn her healthcare providers adequately about known dangerous side effects of its mesh products, and in Count II she alleges that Coloplast failed to ensure its products did not pose a significantly increased risk of injury. These theories and allegations are fairly characterized as demands for relief made in the alternative in separate counts as contemplated by Federal Rule of Civil Procedure 8(a)(3) &(d)(2).

CONCLUSION

For the above-stated reasons, Defendant Coloplast Corporation's motion to dismiss is **DENIED**. Counts I through V and Plaintiff's prayer for punitive damages remain pending, though Count VI will not be recognized as a separate, numbered claim.

IT IS SO ORDERED.

Dated: September 22, 2020.

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GILBERT C. SISON
United States Magistrate Judge